REMARKS

The last Office Action, dated 3/29/04 has been carefully considered, as well as the Examiner's advisory office action. A telephone interview was conducted subsequent to the receipt of the advisory action circa Sept. 5, 2004. Accordingly, the Applicant is submitting the following comments as a summary of the interview with the Examiner. During the interview, the Examiner explained why he believes specific references provide a motivation to combine them, and do not teach in the opposite direction. The Applicant suggested that the Examiner is improperly using hindsight in concluding that references teach or suggest their combination, as the combination claimed is a more complex solution to the problem that the reference attempts to solve. The Examiner stated he would consider evidence in the form of a Rule 132 declaration in support of the Applicants position on this and other issues. The nature of the expected results was discussed, as the Applicant believes the Examiner, among other issues, improperly considers flexibility to be a variable, when it does not appear as a claim element. The Examiner felt that unexpected results might be sufficient to rebut a prima facie case of obviousness that he asserts, but must review this issue with his supervisor. The Applicant appreciates the Examiners in depth discussion of his position on the teachings of the references, as well as the guidance as to what points might be overcome with a sufficient declaration.

It is believed that the above amendments to the claims are fully responsive to overcome the Examiner's objections to claims, 73 and 85, and rejections on the basis of 35 U.S.C. §112 second paragraphs to claims 67, 74, 79. It is believed that the new claims submitted herein are patentable, not withstanding the Examiner's prior rejections under 35 U.S.C. §103 as applied to prior claims 67-84. As the new claims are constructed largely to overcome the Examiners objections and rejections under 35 U.S. C §112, but are directed at essentially the same elements and limitations as the earlier presented claims, the Applicant does not believe a new a new search is required.

Again, the Applicant wishes to stress that they have discovered that the blends of homopolymer, block copolymers and nanoparticles offer previously unidentified benefits

in the manufacture and use of tubing for medical catheters. Specifically, at least two of the following three benefits are achieved, depending on the specific composition:

1. Achieve an intermediate elastic modulus, between that of the components of the polymer blend, yet without a loss of toughness, and in some instances increased toughness (for specific compositions)

2. Improvement in a lower propensity to retain dirt

3. Improved dimensional stability in the process of extruding narrow diameter, thin wall tubing

The argument that these are novel and unexpected properties are supported by the enclosed Rule 132 declaration, specifically, paragraphs 15 – 18 inclusive.

It is noted that the majority of the claims previously presented claims (67, 68, 71-80, 83-85) where rejected under 35 U.S.C. § 103 as being unpatentable over Bagaoisan (U.S. Pat. No. 6,270,477) in view of Beall (U.S. Pat. No. 5,578,672) while the remainder of the claims (70, 71, 81, 82) where rejected over Bagaoisan (U.S. Pat. No. 6,270,477) in view of Beall (U.S. Pat. No. 5,578,672)) and in further review of Tse (U.S. Patent No. 4,717,618). The Examiner is requested to reconsider the propriety of the 35 U.S.C. §103 rejections in presenting a prima fascia argument for obviousness with respect to the new claims as:

1. Bagaoisan and Beall do not provide a motivation to combine, and are therefore improper as a basis for a 103 rejection, see *Ex parte Levengood*, 28 USPQ 2d 1300, 1301–02 (B.P.A.I. 1993), holding that "Accordingly, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent Applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent Applicant has done."

2. Bagaoisan and Beall are not properly combined as they teach away from each other

3. Bagaoisan, Beall and Tse are not properly combined as they teach away from each other.

The aforementioned telephone interview suggests a difference of opinion between the Examiner and the Applicant as what the prior art reasonably suggests or teaches to one of ordinary skill in the art at the time the application was filed, that is without the application of hindsight as to the teachings and claims of the Applicants invention. The Applicants position on the lack of a motivation to combine, as well as their teaching away from each other is supported by evidence in the form of a Rule 132 declaration, specifically paragraphs 12- 15 inclusive. Further, the Applicant wishes to remind the Examiner that even if Bagaoisan can be interpreted to read that it would be desirable to stiffen or reinforce a polymer for one portion of the catheter, such as by adding nanocomposite or other filler, **this would still not provide a motivation to practice the Applicants invention,** but rather would motivate one to add a filler to a single polymer, not the more complex invention of a high and low modulus polymer when the motivation was to obtain a higher modulus. This is because it would take more filler to reinforce the blend of the two polymers, as well as the added complexity of mixing three, not two components, for example thoroughly and in the right proportion.

4. Assuming, for the sake of argument, that the Examiner has made a sufficient case for non-obviousness to establish a prima fascia case of obviousness, the weight of the evidence in the Applicant's original specification overwhelmingly supports a finding of non-obviousness. Specifically, the Applicant has discovered new result effective variable, which produce results that are themselves unexpected in light of the prior art.

Further information is presented to satisfy the requests of the Examiner in the advisory action, as well as point out apparent misunderstanding between what the Applicant contends is evidence versus argument in the prior response to the after final office action response of June 29, 2004. Accordingly, the Applicant is also submitting evidence in the form of a Rule 132 declaration supporting their position with respect to point 4. As the advisory action and subsequent discussion indicate to the Applicant that

the Examiner has misapplied case law with respect to point 4, additional explanation follow as references to the applicable paragraph.

As to the Examiners answer in paragraph 2 of the advisory action, support for the Applicant's position is found in paragraph 12, 13 and 15 of the rule 132 declaration.

As to the Examiners answer in paragraph 3 of the advisory action, the Applicant contends that the Examiner has misconstrued the reference to suit the narrow purposes of his argument, supra. The tip of the catheter is merely the terminal portion of the tube, to assert otherwise is to make a distinction without a difference that would be meaningless to one of ordinary skill in the art reading such a reference. The Examiner is improperly using hindsight when he construes one portion of a reference as broadly as possible as grounds for rejecting a claims, but another portion narrowly, ignoring aspects that clearly teach away from the claimed combination. Support for the Applicant's position is found in paragraph 12 and 13 of the Rule 132 declaration. The Examiner is reminded of additional arguments, supra, as to why the references are not combinable as suggested, and actually teach away from each other.

As to the Examiners answer in paragraph 4 of the advisory action, evidence that hardness is equivalent to modulus is submitted as on page 264, section 10-3 of Principles of Polymer Science, by Rodriguez, a widely used college level textbook in Polymer Science and Engineering Curriculums. As to Examiners request for "evidence that lubricity is related to dirt retention as Applicant indicates in the first three lines of page 14", the Applicant has not made this contention as part of the argument.

The Examiner state in paragraph 5 of the advisory action that the "result effective variable is flexibility". Flexibility of the tubing is a function of the modulus of the material and the cross sectional area. The only variables, which must be in the claims, are the components of the blend and their relative proportions. For the Examiner to apply the case law stated he must show that the prior art teaches that the compositions and proportion ranges are known to produce all of the utilitarian properties discovered by the Applicant and described in the disclosure. The Examiner has not met this burden. The Examiner is directed to paragraph 17 of the enclosed declaration as to what balance of

mechanical properties are unexpected, and why, as well as to paragraph 18 with respect to the other unexpected physical properties.

Arguments 4 and 5, of the Applicant previous response, infra, are presented again as they were apparently not considered in the advisory action.

4. Assuming, for the sake of argument, that the Examiner has made a sufficient case for non-obviousness, the weight of the evidence in the Applicant's original specification overwhelmingly rebuts such arguments.

A. Examiners assertion that the Applicant has merely optimized within a known range is without basis, as the prior art does not teach the variable or the property it improves.

With respect to original claim 79, the Examiner exerts that *In re Boesch* applies in that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results" (page 11, paragraph 13). The Applicant contends that In Re Boesch in not applicable, as discovering the optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results.

The prior art does not teach the result effective variable, to wit; that nanocomposite particles (the variable being the amount of nanocomposite) when added to a blend of a homopolymer and a block copolymer provides an improvements to the following results: 1) dirt retention, 2) dimension stability reduce and 3) toughness, which would otherwise decrease from that of the pure unfilled polymer with the lower modulus on blending with the homopolymer and a reinforcing filler.

Further, in rejecting the Applicants earlier argument with respect to originally submitted claims 74 and 79, the Examiner states (p. 2, paragraph 16 of the last office action) that the Applicant has not met the burden on the Applicant that these results are in fact unexpected and unobvious and of both statistical and practical significance, citing *Ex parte Gelles.* The Applicant categorically rejects this contention on the following basis:

B. Assuming the Examiner's assertion is proper, the Applicant has already met any alleged burden of showing that the results are unexpected

Ex part Gelles is only applicable when the Examiner has indeed made a *Prima facie* case of obviousness based on the prior art disclosing a result effective variable. Further, even if the prior art disclosed nanoparticles as being a result effective variable for the specific properties discovered by the Applicant, *Ex parte Gelles* is not applicable under *In re Soni*, 34 USPQ 2d 1684, 1687 (Fed. Cir. 1995. *In Re Soni* established that the original specification can be sufficient to show unexpected results, stating

> *"Mere improvement in properties does not always suffice to show unexpected results. In our view, however, when an Applicant demonstrates substantially improved results, as Soni did here, and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary. "*
>
> *"Consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results."*

The court further stated that:

> *"The principle applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results."*

The Applicant has specifically met the criteria set forth in *In Re Soni,* by 1) described unexpected benefits in the specification, and 2) making a comparison with the closest prior art. The Applicant states is his specification that the benefits are:

> *"This invention is directed primarily toward those medical applications such as catheters and balloons requiring improvements in many mechanical and other properties such as the balance between stiffness and flexibility, dimensional stability, and less tacky surfaces to decrease the tendency for the material to pick up dirt and other contaminants, and lubricity for ease of travel through the tube."*

The Applicant states in paragraph 52, among other places, that the results are indeed unexpected:

" The present invention provides a means for combining of nanocomposite reinforced polymers with pure Nylon based materials for the purpose of yielding mechanical and other property balances that are new and unexpected while also being uniquely predictable."

In addition, paragraph 69:

"[0069] The Nylon 11 nanocomposite which was blended with the Pebax 7233 produced a resultant polymer having intermediate stiffness. However, it was less ductile than either of the two individual blend components. It was determined that the 50/50 blend was inferior to the blend of Nylon 12 and Pebax 7233. This was a genuinely unexpected result",

In addition, paragraph 77:

"It has also been determined that some copolymers provide new and unexpected values for mechanical properties such as toughness"

In summary, the Applicant has discovered properties that are substantially improved over the prior art, as the prior art is silent on the properties of toughness, dirt retention and dimensional stability, that improved by the novel claimed tubing as defined by its composition. Further the closest prior art has been compared in the specification via tabular data showing various physical properties of tubing fabricated without either of the particular optimum homopolymer, PEBAX, or provides data for the nanocomposite reinforced homopolymer only. For examples, see Tables 4-8, wherein ++, as indicated by the legend in Fig. 2, signifies much improved properties for various nanocomposite compositions.

Therefore, in light of the more detailed arguments and evidence made herein and in the after final response, it is respectfully submitted that the new claims 86-108 clearly and patentably distinguish over the prior art, since it is believed that the construction defined in these claims differs essentially and in an unobvious, highly advantageous manner from the constructions disclosed in the references. Applicant believes that combining the references discussed above, and those asserted in earlier office actions, would not lead to the claimed invention, in that the present invention does not merely employ the known substitution of equivalents but rather employs a new, non-obvious combination to accomplish the objectives set out in the present application.

Should the Examiner consider necessary or desirable any formal changes anywhere in the specification, claims and/or drawing, then it is respectfully asked that such changes be made by Examiner's Amendment, if the Examiner feels this would facilitate passage of the case to issuance. Alternatively should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, he is invited to telephone the undersigned.

Respectfully submitted:

By: _____ on 9/27/2004

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Attachments:
1) Rule 132 Declaration by Daniel Roberts , 10 pages
2) Title Page and p.264, Principles of Polymer Science, R. Rodriguez, 2nd Edition McGraw-Hill, N.Y. , 2 pages .

PRINCIPLES OF POLYMER SYSTEMS

Second Edition

FERDINAND RODRIGUEZ
Professor of Chemical Engineering
Cornell University

HEMISPHERE PUBLISHING CORPORATION *Washington New York London*

McGRAW-HILL BOOK COMPANY *New York St. Louis San Francisco Auckland Bogotá Hamburg Johannesburg London Madrid Mexico Montreal New Delhi Panama Paris São Paulo Singapore Sydney Tokyo Toronto*

10-3 HARDNESS

The most common measure of hardness is the distance into the material that a steel ball will penetrate under a specified load. A spring-loaded, ball-tipped indenter may be used so that the stress is not a linear function of penetration. Since the measurement is basically a compressive modulus, one expects stiff materials to be hard and flexible materials to be soft. In choosing a material for a gasket, hardness often is the only specification listed.

Surface hardness is also measured by scratch and abrasion resistance. As a rule, polymer systems cannot approach the surface hardness of silica glass, which is itself a highly cross-linked structure. Some highly cross-linked laminates do have scratch resistance nearly like that of glass.

10-4 DENSITY

Polymers and other ingredients of polymer systems are sold on a weight basis. However, in most applications they compete on a volume or strength basis. On a strength-volume basis a reinforced plastic sheet may prove much more economical for an aircraft seatshell than a metal sheet that sells for one one-hundredth as much on a pound basis. Several factors affect density including pressure, temperature, and crystallinity.

It has been pointed out that specific volume increases with temperature for polymers, especially where melting occurs. Since crystallinity involves a closer packing of molecules than glassiness, density can be used to measure crystallinity. The specific gravity of polyethylene, for example, varies from 0.86 (extrapolated from the melt) when amorphous to 0.98 when highly crystalline at 25°C [4]. The effect of pressure is important in molding processes where the high molding pressures alter the dimensions of a piece from what they will be at one atmosphere. High pressures that increase density also increase viscosity, because less "free volume" is available for segmental motion (see Sec. 7-5). In a molding operation just above the normal melting temperature, a high pressure may induce crystallization, which stops flow altogether. In Fig. 10-2 the compressibility of an amorphous polymer, polystyrene, is shown together with the compressibility of branched and linear polyethylene. Compressibility is expressed here as the change in volume $\Delta V/V_R$, where V_R is a reference volume at 1 atm and 75°F (23.9°C). The sudden change in volume with pressure for polyethylene is due to crystallization. The change is greater with linear than with branched polymer, because the degree of crystallinity induced is greater. Also illustrated in Fig. 10-2 is the fact that compression of a polymer is time-dependent too. When polystyrene is injection-molded at a pressure of 10,000 psi (69 MPa), there can be a significant difference in final dimensions of the piece depending on the length of time the melt is under pressure before cooling below T_g.

The atomic makeup of polymers affects density in much the same way it does low-molecular-weight compounds (Table 10-1). It should be remembered that a typical linear polymer is 15 to 30% more dense than the corresponding monomer.

The density of final compounded products usually is the weighted average of the ingredients (provided none are volatilized during fabrication). Some examples are given in Table 10-2.